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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,712	09/13/1999	ROBERT W. ESMOND	0609.4440002	4740

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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/394,712	Applicant(s) ESMOND ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8 and 13-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *8 and 13-19* is/are allowed.

6)☒ Claim(s) *1-2,7 and 20-29* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for the Continued examination(RCE) acknowledged

1. The request filed on April 03, 2001 for a RCE under 37 CFR 1.114 based on parent Application No. 09/394,712 is acceptable and a RCE has been established. An action on the RCE follows.

Status of Application

2. The prosecution of this application has been suspended due to the potential interference (request filed on Jan. 02, 2002). However, there are some deficiency was found in the instant claims and the claims are not allowable at this time. Thus, new office action is issued and it supercedes any previous office action.

New Matter

3. The amendment filed 11/22/2000(see paper no.7) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. Claims 1-2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added material which is not supported by the original disclosure is as follows: In claim 1, the proviso

that said agent is not insulin-like growth factor or a dopamine agonist. Amending claims with the said negative statement can not be used to obviate the previous art rejection because support for the said proviso can not be found in the original disclosure.

Allowable Subject Matter

5. Claims 8 and 13-19 are allowed.

6. **Reasons for the allowance**: The following is a statement of reasons for the indication of allowable subject matter: US 4,775,665 teaches a method for treating neurological disorders such as Alzheimer's disease using a composition amino acids and insulin releasing carbohydrates. It teaches away from instant invention which is claiming a method comprising restricting carbohydrate diet along with therapeutic modality such as dopamine agonists. Thus, the claimed subject matter is not anticipated nor obvious over the prior art of the record.

7. Claims 2 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 20, 21,22, 25 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkerson (US5,326,770).

Wilkerson teaches a 2, 4-thiazolidinedione derivatives(e.g. pioglitazone or a pharmaceutical salt thereof, see column 3, lines 1-10) useful in treating mental disturbances, mental retardation, and memory disorders such as Alzheimer's disease or dementia and m see abstract and column 1 lines 25.

Even though Wilkerson did not mention the biological pathway involving insulin level, the instant claims are not patentably distinct because the limitation recited in the preamble(i.e. increasing insulin sensitivity) is inherent feature which is naturally occurring when the patented composition is used in treating Alzheimer's disease and improving memory. Thus, the claims are anticipated by the cited reference.

10. Claim 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Maack et al(WO9513823) or Baker et al(US5,534,615).

Maack et al teach a method of treating Alzheimer's disease using insulin-like growth factor, see claim 1.

Baker et al also teach that insulin-like growth factor that is known as a neurotrophic factor, enhances neuronal survival and growth and thus, it is used in the treatment of Alzheimer's disease, see column 2, lines 39-45.

Thus, the claimed subject matter is not patentably distinct over the cited references.

As to claim 20, it is noted that the recited limitation(i.e. improving mentation) can be achieved naturally when the insulin-like growth factor is administered to treat Alzhiemer's disease because it is the main characteristic of the Alzheimer's disease and thus, one would have been envisaged the improvement on Alzheimer's disease inherently come along with the improvement on mentation of a patient. Thus, the claim 20 is properly included in this rejection.

11. Claim 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wurtman(US 4,775,665) or Dubach et al(WO96/03087).

Wurtman (US'665) teaches a synergistic combination of dopamine agonist comprising choline and tyrosine useful in treating Alzheimer's disease, see abstract, Table I at column 5 and column 1, lines 24-60.

Thus, the claimed subject matter is not patentably distinct over the cited references.

As to claim 20, it is noted that the recited limitation(i.e. improving mentation) can be achieved naturally when any dopamine agonist is administered to treat Alzhiemer's disease because it is the inherent characteristic of the Alzheimer's disease and thus, one would have been envisaged the improvement on mentation of an Alzheimer patent when Alzheimer's disease gets improved. Thus, the claim 20 is properly included in this rejection.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 7, 23-24, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkerson in view of Olesfsky (US 5,478,852).

As mentioned earlier in 102 rejection(supra), Wilkerson teaches a 2,4 thiazolidinedione derivatives effectively used in the treatment of Alzheimer's disease, mental disturbances, mental retardation, and memory disorders such as dementia. Even though Wilkerson broadly teaches the generic formula I of 2,4-thiazolidinedione, he has not specifically included triglitazone or other claimed compound(recited in claims 24-25, 28-29) as a preferred species in his patent.

However, it would have been obvious to one of ordinary skill in the art to substitute pioglitazone with triaglitazone or the compound of instant claim 24-25(its salt) and 28-29 when Wilkerson is taken in view of Olesfsky because Olesfsky teaches pioglitazone and its functionally equivalent species such as triaglitazone in his patent, see column 14, 60-column15, 30.

One would have been motivated to do so because extension of therapeutic modality is always desirable and beneficial to the users who could advantageous select the drug based on their specific needs and preference. The minor variations including the selection of drug among the functionally equivalent

species, optimal dosages, or variable formulations in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

14. The claims 8 and 13-19 are allowed. The claim 2 is allowable.

15. The claims 1, 4 and 20-29 are rejected.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne .Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
February 5, 2003
Art unit 1614